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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,361	10/06/2000	Alexander Gaiger	210121.465C2	9832

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	**PAPER NUMBER**
1644	18

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/684,361	Gaiger et al.
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 6, 7, and 46-60* is/are pending in the application.

4a) Of the above, claim(s) *46 and 55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6, 7, 47-54, and 56-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Applicant's election of Group I and the species SEQ ID NO:144 in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)

2. Claims 10-45,5,8,9,46,55, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 13.

3. Applicant's election of the species GM-CSF in Paper No. 17 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)

4. Claims 1,6,7,47-54,56-60 are under consideration. Claims 2-5,8-45 have been canceled.

5. The abstract of the disclosure is objected to because it does not disclose the claimed invention, wherein said invention comprises the polypeptide of SEQ. ID. No:144. Correction is required. See MPEP § 608.01(b).

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any
> person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1,47-52,56-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed

invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed peptides.

The instant claims encompass a variant peptide wherein said peptide encodes an immunogenic peptide wherein said peptide binds MHC of an animal (eg. T cell binding requires MHC binding of the peptide) wherein said variant differs in amino acid sequence from specific peptides disclosed in the specification. The claims encompass a variant peptide wherein said peptide encodes an immunogenic peptide wherein said peptide binds antisera against WT1. There are thousands of different mammals that express structurally differing MHC molecules that bind different, largely nonoverlapping sets of peptides and the specification provides written description of peptides only derived from mouse or human. In addition, regarding claims that encompass immunogenic peptides which bind human MHC, the art recognizes that there are hundreds of different allotypes of MHC molecules found in humans, wherein each allotype binds a unique set of peptides not bound by a different allotype. Similarly, the specification provides written description of particular peptides that bind WT1 antisera. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has disclosed specific immunogenic peptides which bind MHC or WT1 antisera, while claiming variant peptides which bind any MHC or antisera against WT1 from any mammal. The Federal Circuit has held that if an inventor is "unable to envision

the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

8. Claims 1,6,7,47-54,56-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed immunogenic peptides. The instant claims recite that the claimed peptide is immunogenic. However, there is no evidence of record that the claimed peptides are actually immunogenic. Regarding the peptide of SEQ. ID. NO: 144, there is no actual evidence provided in the specification that said peptide is immunogenic with regards to stimulation of T cells. The specification discloses that the peptide of SEQ. ID. NO: 144 has a particular score using a formula for allegedly predicting binding of a peptide to HLA A24. However, there is no empirical evidence provided using actual assays that demonstrates that said peptide is immunogenic. Furthermore, Deavin et al. disclose that algorithms for predicting T cell epitopes generally do not work (see abstract). Thus, the state of the art is such that is unpredictable in the absence of appropriate evidence whether the claimed peptides are actually immunogenic. Undue experimentation would be required of one skilled in the art to practice the instant invention

using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1,6,7,47,52,56 are rejected under 35 U.S.C. 102(b) as being anticipated by Herlyn et al. (WO 95/29995).

Herlyn et al. teach a peptide comprising SEQ. ID No:144 (eg. see page 19, last paragraph wherein SEQ. ID. No:144 is found in amino acids 1-181 of human WT1), wherein said peptide is immunogenic (eg. it induces antibodies, see page 20). The pharmaceutically acceptable excipient is the buffer that said peptide is dissolved in (see page 20, example 2).

11. Claims 1,6,7,47,48,52,56,57 are rejected under 35 U.S.C. 102(e) or 102(a) as being anticipated by Call et al. (US Patent 5,726,288).

Call et al. teach an immunogenic peptide comprising SEQ. ID No:144 (eg. see column 16, wherein polypeptide refers to WT1), wherein said peptide is in a pharmaceutically acceptable excipient (eg. it is to be used therapeutically, see column 16, penultimate paragraph, first sentence). Call et al. teach peptides encompassed by the "variant" recited the claims wherein said variants are used with a non-specific immune response enhancer (see Example 4).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1,6,7,47-52,56-60 are rejected under 35 U.S.C. 103(a) as obvious over Herlyn et al. (WO 95/29995) in view of Jager et al. (US Patent 6,096,313).

Herlyn et al. teach a peptide comprising SEQ. ID No:144 (eg. see page 19, last paragraph wherein SEQ. ID. No:144 is found in amino acids 1-181 of human WT1), wherein said peptide is immunogenic (eg. it induces antibodies, see page 20). The pharmaceutically acceptable excipient is the buffer that said peptide is dissolved in (see page 20, example 2). Herlyn et al. does not teach a composition containing the claimed peptide and GM-CSF. Jager et al. teach use of GM-CSF as an adjuvant and compositions containing GM-CSF and a peptide (see column 6, second paragraph and column 1, first paragraph and claim 1). Jager et al. teach that GM-CSF can enhance the immune response against an antigen (see column 6, second paragraph). GM-CSF enhances a T cell response in a patient (eg. see example 4). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed inventions because Herlyn et al. teach the peptides recited in the claims while Jager et al. teach use of GM-CSF as an adjuvant and that GM-CSF can enhance the immune response against an antigen. One of ordinary skill in the art would have been motivated to do the aforementioned because Jager et al. teach that GM-CSF can enhance the immune response against an antigen (column 6, second paragraph). Thus, using said composition, a routineer would have achieve superior results when immunizing animals to produce antibodies as per Herlyn et al.

14. Claims 1,6,7,47-51 are rejected under 35 U.S.C. 103(a) as obvious over Call et al. (US Patent 5,726,288) in view of Jager et al. (US Patent 6,096,313).

Call et al. teach an immunogenic peptide comprising SEQ. ID No:144 (eg. see column 16, wherein polypeptide refers to WT1), wherein said peptide is in a pharmaceutically acceptable excipient (eg. it is to be used therapeutically, see column 16, penultimate paragraph. first sentence). Call et al. teach peptides encompassed by the "variant" recited in the claims (see Example 4). Call et al. does not teach the claimed

composition containing GM-CSF. Jager et al. teach use of GM-CSF as an adjuvant and compositions containing GM-CSF and a peptide (see column 6, second paragraph and column 1, first paragraph and claim 1). Jager et al. teach that GM-CSF can enhance the immune response against an antigen (see column 6, second paragraph). GM-CSF enhances a T cell response in a patient (eg. see example 4). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed inventions Call et al. teach the peptides recited in the claims while Jager et al. teach use of GM-CSF as an adjuvant and that GM-CSF can enhance the immune response against an antigen. One of ordinary skill in the art would have been motivated to do the aforementioned because Jager et al. teach that GM-CSF can enhance the immune response against an antigen (column 6, second paragraph). Thus, using said composition, a routineer would have achieve superior results when immunizing animals to produce antibodies as per Call et al.

15. No claim is allowed.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644

RONALD B. SCHWADRON
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GROUP 1600